



533 Rec'd PST/PTO 10 AUG 2001
c8-13-81
#7 1615
LB

EXPRESS MAIL INDICATE

Date 8/10/01 Label No. EL 903057145-45

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

PLEASE CHARGE ANY DEFICIENCY UP TO \$300.00 OR CREDIT ANY EXCESS IN THE FEES DUE WITH THIS DOCUMENT TO OUR DEPOSIT ACCOUNT NO. 04-0300

B.W. LEE
Name (Print)

B.W. Lee
Signature

Customer No.:



Docket No.: 1946/1D864-US1

07278

PATENT TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

David Gschneidner, et al.

Serial No.: 09/762,067

Filed: January 31, 2001

For: **COMPOUNDS AND COMPOSITIONS FOR DELIVERING ACTIVE AGENTS**

RECEIVED

SEP 12 2001

TECH CENTER 1600/2900

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

Sir:

In order to comply with 37 CFR 1.97 and 1.98, attached hereto is a copy of Form PTO-1449 and copies of the documents listed thereon.

In accordance with MPEP Sections 609 and 707.05(b), it is requested

that each document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing Form PTO-1449 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

Since these documents are being submitted before the first Office Action has been received, no fee is due. The Commissioner is authorized to charge any additional fees required in connection with this Petition or to credit any overpayment to Deposit Account No. 04-0100.

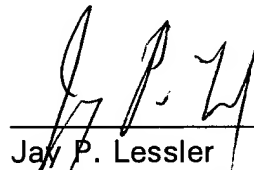
The present Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56, but the citation of such document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and 1.106(b) and, in the course of each search, will review for relevance every document cited on the attached form even if not

initialed.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

Dated: August 10, 2001



Jay P. Lessler
Registration No. 41,151
Attorney for Applicant(s)

DARBY & DARBY
805 Third Avenue
New York, NY 10022
(212) 527-7700

Form PTO-1449 (Rev. 10-92) [modified] INFORMATION DISCLOSURE CITATION IN AN APPLICATION (use several sheets if necessary)	Docket No.: 1946/1D864-US1	Application No.: 09/762,067
IDS Filed 6/01	Applicants: Gschneider et al.	
	Filing Date: 1/29/2001	Group Art Unit:

RECEIVED

SEP 12 2001

TECH CENTER 1600/2900

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME OF PATENTEE OR APPLICANT	CLASS	SUB- CLA SS	FILING DATE
	4 0 6 1 4 6 6	12/6/977	Sjoholm et al.	436	535	10/14/75
	4 1 4 7 7 6 7	4/3/79	Yapel	424	22	9/30/77
	4 2 3 8 5 0 6	12/9/80	Stach, deceased et al.	424	319	6/29/78
	4 4 4 2 0 9 0	4/10/984	Kakeya et al.	424	178	3/24/81
	4 4 6 2 9 9 1	7/31/84	Higuchi et al.	424	177	6/11/82
	4 7 5 7 0 6 6	7/12/87	Shiokari et al.	514	210	7/12/88
	4 8 7 3 0 8 7	10/10/89	Morishita et al.	424	433	10/10/89
	5 0 6 6 4 8 7	11/19/91	Morelle et al.	424	68	9/12/89
	5 3 5 2 4 6 1	10/4/94	Feldstein et al.	424	493	10/4/94
	5 4 5 5 3 3 5	10/3/95	Kahane et al.	536	5	4/8/94
	5 7 0 5 5 2 9	1/6/97	Matyus et al.	514	541	10/11/91
	4 8 9 5 7 2 5	01/23/90	Kantor et al.	424	455	04/04/98
	4 9 2 5 6 7 3	5/15/90	Steiner	424		8/1487
	4 9 7 6 9 6 8	12/11/90	Steiner	424	491	02/24/89
	4 9 8 3 4 0 2	01/08/91	Steiner	424	491	02/24/89
	5 4 0 1 5 1 6	03/28/95	Milstein et al.	424	491	04/22/93
	5 4 4 3 8 4 1	08/22/95	Milstein et al.	424	451	07/27/92
	5 4 4 7 7 2 8	09/05/95	Milstein et al.	424	490	12/16/93
	5 4 5 1 4 1 0	09/19/95	Milstein et al.	424	490	04/22/93
	5 5 4 0 9 3 9	07/30/96	Milstein et al.	424	491	04/25/94
	5 5 4 1 1 5 5	07/30/96	Leone-Bay et al.	514	2	04/22/94
	5 5 7 8 3 2 3	11/26/96	Milstein et al.	424	499	06/14/93
	5 6 0 1 8 4 6	02/11/97	Milstein et al.	424	499	05/05/95
	5 6 2 9 0 2 0	05/13/97	Leone-Bay et al.	424	489	04/22/94
	5 6 4 3 9 5 7	07/01/97	Leone-Bay et al.	514	563	10/25/94
	5 6 5 0 3 8 6	07/22/97	Leone-Bay et al.	514	2	03/31/95
	5 6 6 7 8 0 6	09/16/97	Kantor et al.	424	484	06/07/95
	5 6 9 3 3 3 8	12/02/97	Milstein et al.	424	451	09/29/94
	5 7 0 9 8 6 1	01/20/98	Santiago et al.	424	184	01/13/95
	5 7 1 4 1 6 7	02/03/98	Milstein et al.	424	490	10/25/94
	5 7 5 0 1 4 7	05/12/98	Kantor et al.	424	491	06/07/95
	5 7 6 6 6 3 3	06/16/98	Milstein et al.	424	489	04/22/94
	5 7 7 3 6 4 7	06/30/98	Leone-Bay et al.	562	444	02/07/97
	5 7 7 6 8 8 8	07/07/98	Leone-Bay et al.	514	2	02/07/97
	R 3 5 8 6 2	07/28/98	Steiner et al.	424	455	08/14/87
e						
	5 7 9 2 4 5 1	08/11/98	Sarubbi et al.	424	85.4	03/02/94
	5 8 0 4 6 8 8	09/08/98	Leone-Bay et al.	562	444	02/07/97
	5 8 1 1 1 2 7	09/22/98	Milstein et al.	424	490	10/24/94
	5 8 2 0 8 8 1	10/13/98	Milstein et al.	424	489	04/28/95
	5 8 2 4 3 4 5	10/20/98	Milstein et al.	424	489	06/07/95
	5 8 4 0 3 4 0	11/24/98	Milstein et al.	424	499	08/30/96

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant	

Form PTO-1449 (Rev. 10-92) [modified] INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(use several sheets if necessary)</i>										Docket No.: 1946/1D864-US1			Application No.: 09/762,067		
IDS Filed 6/01										Applicants: Gschneidner et al.					
										Filing Date: 1/29/2001			Group Art Unit:		
	5	8	6	3	9	4	4	01/26/99	Leone-Bay et al			514	559	04/30/97	
	5	8	6	6	5	3	6	02/02/99	Leone-Bay et al			514	2	02/06/97	
	5	8	7	6	7	1	0	03/02/99	Leone-Bay et al			424	85.1	02/07/97	
	5	8	7	9	6	8	1	03/09/99	Leone-Bay et al			424	85.1	02/07/97	
	5	9	3	5	6	0	1	08/10/99	Leone-Bay et al			424	489	04/21/95	
	5	9	3	9	3	8	1	08/17/99	Leone-Bay et al			514	2	02/07/97	
	5	9	5	5	5	0	3	09/21/99	Leone-Bay et al			514	563	02/06/97	
	5	9	5	8	4	5	7	09/28/99	Santiago et al.			424	490	05/10/95	
	5	9	6	2	7	1	0	10/05/99	Gschneidner et al			554	112	05/09/97	
	5	9	6	5	1	2	1	10/12/99	Leone-Bay et al.			424	85.2	02/06/97	
	5	9	7	2	3	8	7	10/26/99	Milstein et al.			424	491	11/21/94	
	5	9	7	6	5	6	9	11/02/99	Milstein et al.			424	451	04/29/97	
	5	9	8	9	5	3	9	11/23/99	Leone-Bay et al			424	85.2	02/06/97	
	5	9	9	0	1	6	6	11/23/99	Leone-Bay et al			514	563	02/07/97	
	6	0	0	1	3	4	7	12/14/99	Leone-Bay et al			424	85.1	02/06/97	
	6	0	5	1	2	5	8	04/18/00	Kantor			424	491	06/07/95	
	6	0	5	1	5	6	1	04/18/00	Leone-Bay et al			514	56	02/07/97	
	6	0	6	0	5	1	3	05/09/00	Leone-Bay et al			514	559	02/07/97	
	6	0	7	1	5	1	0	06/06/00	Leone-Bay et al			424	85.2	04/23/97	
	6	0	7	1	5	3	8	06/06/00	Milstein et al.			424	464	09/30/97	
	6	0	8	4	1	1	2	07/04/00	Ho et al.			554	114	09/10/96	
	6	0	9	0	9	5	8	07/18/00	Milstein et al			554	112	02/07/97	
	6	0	9	9	8	5	6	08/08/00	Milstein et al.			424	450	12/10/96	
	6	1	0	0	2	8	5	08/08/00	Kantor			514	400	11/11/97	
	6	1	0	0	2	9	8	08/08/00	Leone-Bay et al.			514	563	02/06/97	
	6	1	8	0	1	4	0	01/30/01	Leone-Bay et al.			424	489	06/02/95	
	6	2	2	1	3	6	7	4/24/01	Milstein et al.			424	400	9/29/97	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
						YES	NO
	3 6 9 8 5 3	7/24/69	Spain				
	0 0 3 6 1 4 5	9/23/81	EPO				
	2 0 9 5 9 9 4	10/13/82	Great Britain				
	2 2 6 2 2 3	6/27/87	EP				
	5 7 6 9 4 1	6/19/93	EP				
	2 2 3 9 9 8 0	9/21/90	Japan				
	0 5 1 7 2 1 1	9/12/92	EP				
	0 0 0 7 9 7 9	5/18/00	EO				
	0 0 0 6 5 3 4	2/10/00	WO				
	0 0 0 6 1 8 4	2/10/00	WO				
	0 0 4 8 5 8 9	8/24/00	WO				
	0 0 5 9 8 6 3	10/12/00	WO				
EXAMINER:				DATE CONSIDERED:			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant							

Form PTO-1449 (Rev. 10-92) [modified] INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(use several sheets if necessary)</i>	Docket No.: 1946/1D864-US1	Application No.: 09/762,067
IDS Filed 6/01	Applicants: Gschneidner et al.	
	Filing Date: 1/29/2001	Group Art Unit:

OTHER DOCUMENTS

EAMINER INITIAL	
	Picciola G.: "Sintesi Di Acidi Chiazolinioici E Benzossazinonici E Studio Delle Loro Proprieta Antiniammatorie" IT, Societa Chimica Italiana Pavia vol 31, no. 9 pgs 655-664 and English Translation
	Chem Abs 73548-12-6 (4/1991)
	Chem Abs 70204-54-5 (4/1991)
	Chem Abs 184360 -83-342 (1975) "Solubility and disassociation constants of some alicyclic acids
	Chemical Abstract, Vol. 99(23) Abst. No. 191473h (1983)
	Johansen, Marianne, et al. "The Kinetics of decompn. Of various N-Mannich bases of salicylamide" Int. J. Pharm. (1980), 7(2): 119-27 (1980)
	Riveria, Theresa M. et al. "Oral Delivery of Heparin in Combination with Sodium N-[8-2-hydroxybenzoyl]amino]caprylate: Pharmacological Considerations" Pharmaceutical Research vol 14(12) 1830-1834 (1997)
	Andrea Leone-Bay"4-(4-Salicyloylaminophenyl)butyric Acid as a Novel Oral Delivery Agent for Recombinant Human Growth Hormone" Medi 006, Presented at the American Chemical Society, March 24-28, 1997 New Orleans, LA
	Leone-Bay, A. et al. " The evolution of an oral heparin dosing solution" Drugs of the Future vol 22(8) 885-891 (1997)
	Brayden, D. et al. "Heparin Absorption across the intestine: Effects of Sodium N-[8-2-hydroxybenzoyl]Amino] Caprylate in rat in situ intestinal instillations and in Caco-2 monolayers" Pharmaceutical Research vol 14(12) 1772-1779 (1997)
	Leone-Bay, A. "Acylated non-alpha-amino acids as novel agents for the oral delivery of heparin sodium, USP" Journal of Controlled Release 50: 41-49 (1998)
	Leone-Bay, A. "4-[4-[(2-Hydroxybenzoyl)amino]phenyl]butyric acid as a novel oral delivery agent for recombinant human growth hormone" ; Journal of Medicinal Chemistry vol 39, 2571-2578 (1996)
	Leone-Bay, A. "N-Acylated alpha-amino acids as novel oral delivery agents for proteins" "; Journal of Medicinal Chemistry vol 38, 4263-4269 (1995)
	Leone-Bay, A. "N-Acylated alpha-amino acids as novel oral delivery agents for proteins" "; Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)
	Ho Koc-Kan; et al. " A Practical Synthesis of omega-aminoalkanoic acid derivatives from Cycloalkanones" Synthetic Communication, vol. 26, no. 14: 2641-2649 (1996)
	Gurrieri and Siracusa: "Thermal Condensation of Some alpha-aminoacids with Phthalic Acid" Thermochemica Acta, 7 (1973) 231-239
	Amino Yusuke et al. Chem Pharm Bull 36 pgs 4426-4434 (1988)
	Brown, G. and Foubister, A.J. "Receptor Binding Sites of Hypoglycemic Sulfonylureas and Related[(Acylamino)alkyl][benzoic Acids JmedChem 27, 79-81 1984

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant	